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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,105	11/28/2000	Graham P. Allaway	51320-AA/JPW/MAF	6247

7590 09/23/2004

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,105	ALLAWAY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6,8,9,11,13,17,19,22,26,27,31,36,43 and 48* is/are pending in the application.

4a) Of the above claim(s) *48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 1,6,8,9,11,13,17,19,22,26,27,31,36 and 43.

DETAILED ACTION

The amendment filed on 11/28/2000 has been acknowledged. The previous office Action mailed on May 19, 2004 was vacated. The examiner apologized for the inconvenient caused by this scanning problem inside the office. Now, claims 1, 6, 8-9, 11, 13, 17, 19, 22, 26, 27, 31, 36, 43 and 48 are pending. Applicants are reminded that claim 48 depends on a canceled claim 42. therefore, it is not restricted into any group in the present office action. It will be restricted into a proper group upon the claim is amended properly. Currently, claims 1, 6, 8-9, 11, 13, 17, 19, 22, 26, 27, 31, 36, and 43 are restricted as follow:

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim 1 and 11, drawn to a polypeptide having a sequence corresponding to a portion of a chemokine receptor and a method of using same, classified in class 530, subclass 300.

   II. Claims 6 and 8, drawn to a polypeptide and a composition comprising the polypeptide having a sequence corresponding to a portion of a HIV-1 envelope glycoprotein, classified in class 424, subclass 208.1.

   III. Claim 9, drawn to an antibody or fragment thereof, classified in class 424, subclass 134.1.

   IV. Claims 13 and 17, drawn to a non-chemokine agent and a method of using same, wherein the non-chemokine agent capable of dinging to the chemokine receptor CCR5 and inhibit the fusion of HIV-1 to CD4+ cell, classified in class 530, subclass 351.

   V. Claims 19 and 26, drawn to a molecule comprising a non-chemokine agent linked with a ligand, which is capable of binding to a cell surface receptor rather than the chemokine receptor and a method of using same classified in class 530, subclass 388.22.

   VI. Claim 22, drawn to a molecule comprising a non-chemokine agent linked to a compound, which is capable of increasing the in vivo half-life of the non-chemokine agent, classified in class 424, subclass 78.91.

VII. Claim 27, drawn to a method for determining whether a non-chemokine agent is capable of inhibiting the fusion of HIV-1 to a CD4+, CCR5 + cell by using a cell to cell fusion assay, classified in class 435, subclass 440.

VIII. Claim 31, drawn to non-human transgenic animal, classified in class 800, subclass 8.

IX. Claim 36, drawn to an agent, which binds to a chemokine receptor but does not affect the receptor's capacity to bind to chemokine, classified in class 530, subclass 300.

X. Claim 43, drawn to a method of using same, wherein the agent binds to a chemokine receptor but does not affect the receptor's capacity to bind to chemokine, classified in class 424, subclass 93.1.

2. **The inventions are distinct, each from the other because of the following reasons.**

Inventions I-III, V-VI and VIII-IX are patentably distinct products.

The polypeptide of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptide of Group I comprises a portion of a chemokine receptor, whereas polypeptide of group II is a HIV glycoprotein. They differ in structures and functions, e.g. the chemokine receptor is located on the cell surface and mediate an inflammatory effect and mediate the HIV virus entry, whereas the HIV gp120 is a glycoprotein of HIV envelope protein, which is associated with the virus. Furthermore, it is immunogenic for inducing an antibody against HIV-1virus. The search for polypeptide of a chemokine does not need to search for a HIV glycoprotein in sequence and text. For these reasons, the inventions of groups II and I are patentably distinct.

The polypeptide of group II and I differ from the non-chemokine agent in group III for the following reasons. Polypeptide of Group I is a portion of a chemokine receptor; and the polypeptide of group II is a HIV glycoprotein. In contrast, the non-chemokine agent in group III is an antibody against chemokine receptor. Each of them has different amino acid sequence structure and function. Therefore, they require different structural and text searches, i.e. the search for polypeptide of a chemokine does not need to search for a HIV glycoprotein or search

for an antibody to a chemokine receptor. For these reasons, the inventions of groups I, II and III are patentably distinct.

The polypeptide of group I, II or III differs from the non-chemokine agent in group IV in that each of them has distinct structure and function. For example, the product of group IV is a non-chemokine agent, such as a small peptide ALX40-4C (N-acetyl-nona-D-arginine (Arg) amide), a polypeptide of nine Arg residues stabilized by terminal protection and inclusion of D amino acids, which can inhibit the , a non-chemokine reagent, which inhibits the T tropic HIV infection in CD4+ and CXCR4+ cells as evidenced by Doranz et al. (J. Exp Med. 1997, Volume 186, Number 8, pp. 1395-1400, see abstract). In contrast, polypeptide of Group I is a chemokine receptor; the polypeptide of group II is a HIV glycoprotein; and the Group III is a chemokine receptor antibody. Therefore, they have different structures, which required different search, and are patentably distinct.

The non-chemokine agent in IV differs from the agent in group V or VI in that the main component of group IV is a non-chemokine agen, whereas the non-chemokine agent in group V and VI comprise other component; e.g. the subject matter in group V is a non-chemokine agent linked with a ligand, whereas the subject matter in Group VI is a non-chemokine agent linked with a compound. Therefore, they requires different searches and are patentably distinct

The product of Group VIII differs from any product in Groups I-VI and IX in that it is drawn to a non-human animal, rather than a non-living subject matter. It is structurally and functionally different from any or the product in Groups I-VI and IX. Moreover, they exhibit different status of the art as shown by different classification. Therefore, they are patentably distinct.

The product of Group IX differs from any product in Groups I-VI in that it is drawn to an agent. It can be structurally and functionally different from any or the product in Groups I-VI in that it binds to a chemokine receptor, but does not substantially affect the capacity of the chemokine binding to its receptor. For example, the antibody to the CCR5 receptor as claimed in group III differs from it since anti-CCR5 mAb 2D7 binds to the CCR5, and it influences the function of the chemokine receptor binding to the chemokine as evidence ed by Ruffing et al. (Cellular Immunology 1998, Vol. 189, pp. 160-168, see page 163). The peptide F, which is derived from the HIV gp120 induce the chemotaxis after binding to the chemokine receptor,

however, it influence the chemokine receptor binding to the chemokine as evidenced y Deng et al. (Blood 1999, Vol. 94, No. 4,, pp. 165-1173, see page 1166-1168). Therefore, it is patentably distinct from other subject matter in groups I to VI.

Inventions of group VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method of group VII is drawn to a method for determining a non-chemokine agent, whereas the method of group IX is to use a no-chemokine agent. Each method comprises different steps and is used for the different purposes. Products. For these reasons, the different groups of Inventions are patentably distinct.

Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide in group I can be used to induce chemotaxis rather then inhibition o fHIV-1 infection.

Inventions II and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used to immunize an animal to produce an antibody, as opposed to being used as an agent for inhibiting HIV-1 or HIV-1 infected cell fused with a CD4+ cell.

Inventions IX and X are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

product as claimed can be made by another different process, such as inhibiting the inflammatory reaction, rather than inhibiting HIV infection.

Because these inventions are distinct for the reasons given above, the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Affirmation of this election must be made by applicant in replying to this Office action. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
09/05/2004

JAMES HOUSEL 9/20/04
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